SENSUS™

PAIN MANAGEMENT

User Manual

GET RELIEF

GET ACTIVE

GET SLEEP

NEUROMetrix®

TABLE OF CONTENTS

Chapter 1: Overview 3
Introduction 3
What You Should Have Received 4
Device Components 6

Chapter 2: Quick Start Instructions 7

Chapter 3: SENSUS Device Basics 9
Checking Battery 9
Charging Battery 9
Attaching Electrode 11
Device Placement 12

Chapter 4: Configuring SENSUS 13

Chapter 5: Pain Therapy with SENSUS 14
Preparing for Therapy Session 15
Starting Therapy Session 15
Adjusting Intensity During Therapy Session 16
Ending Therapy Session 17
Setting Continuous Mode 18

Chapter 6: Using SENSUS During Sleep 19

Chapter 7: SENSUS Electrodes 19

Chapter 8: Skin Care 21

TABLE OF CONTENTS CONT.

Chapter 9: Maintenance, Safety, and Service 24
Maintenance 24
Cleaning 24
Device Storage 24
Disposal 24
Limited Warranty 24

APPENDIX A: Indicator Light 27
APPENDIX B: Troubleshooting 28-31
APPENDIX C: Frequently Asked Questions 32-33
APPENDIX D: Alternate Sites 34
APPENDIX E: Technical Specifications 35-37
APPENDIX F: Prescribing Information 38-41
APPENDIX G: Symbols 42
APPENDIX H: Electromagnetic Compatibility Declaration 43

Chapter 1: Overview

Introduction

The SENSUS™ Pain Management System provides relief from chronic pain. It consists of a device and an electrode that attaches to the device. The device is worn on your upper calf, just below the knee. Your doctor may prescribe one or two SENSUS devices. If you have been prescribed two devices, they can be used at the same time (one on each leg).

SENSUS provides pain relief by comfortably stimulating your sensory nerves, which decreases the perception of pain. Each therapy session lasts 60 minutes and is initiated by pressing a button on the device. Pain relief usually begins within 15 minutes and may last for 30 minutes after the session ends. At the end of a session, you may either leave the device on your leg or remove it until you are ready for another session. You may start a therapy session anytime you need pain relief.

It is important that you use SENSUS correctly in order to gain the most benefit. You should review this User Manual carefully. Chapter 2 provides basic instruction on how to set up and use the device. Chapters 3–5 provide detailed instruction on device use. Chapter 6 provides information on using the device during sleep. Chapter 7 provides tips for taking care of the electrodes. Chapter 8 provides information on preventing skin irritation, particularly if you have sensitive or dry skin. Appendix C provides answers to frequently asked questions.

If you have any questions about how to use SENSUS please contact your supplier, call NeuroMetrix customer service at (888) 786-7287, or speak with your doctor.

What You Should Have Received

Upon receiving your SENSUS Pain Management System you should inspect its contents to make sure all of the following are included and undamaged (see Figure 1).

A. SENSUS Device*

B. Small and Large Replacement Straps*

C. USB Cable*

D. AC Adapter*

E. User Manual

*Two are provided if your doctor prescribed two devices.

You may also have received 1 or more electrode packages (Figure 2). If any of the items appear damaged, contact your supplier.

ONLY USE SENSUS ELECTRODES MANUFACTURED BY NEUROMETRIX, INC.

Figure 1.

Figure 2.

Device Components

The device has the following components:

1. Push button
2. Indicator light
3. Adjustable Velcro® strap
4. Two electrode connector snaps
5. USB port

Chapter 2: Quick Start Instructions

The following instructions will help you start using SENSUS quickly. For detailed instructions, please review Chapters 3-8. These instructions are also available in video format. Please visit www.SENSUSRx.com and click on the *Resources for Users* tab.

Step 1: Check Battery

Briefly press and release the button.

Indicator Light Flash

- charged
- recharge

Step 2: Attach Electrode

Snap in a new electrode.

Step 3: Place Device

Remove liner and place the device on your upper calf 1-2 inches below knee; the exact position is not critical.

Step 4: Configure

Press and hold button for 10 seconds until the indicator light is steady green. Briefly press the button every time you feel a tingling sensation under the electrode. When the light turns off, configuration is complete. This should take about 1 minute.

Step 5: 60 Minute Therapy Session

Press and hold button for a few seconds, release the button when the indicator light starts blinking green. Stimulation should feel strong but comfortable.

To decrease: Briefly press the button. Each press will decrease the intensity.

To increase: Press and hold the button. The intensity will increase while the button is held down.

To stop therapy, tap center compartment twice while keeping leg still.

Ventilate skin after wearing SENSUS for several hours and after overnight use. Watch for skin irritation.

Helpful Tips

- Entire electrode should contact skin
- Every few hours and before sleep, make sure strap is snug
- Every 2-3 days or if gel is dry, run electrode under water
- Change electrode every 2 weeks

If you need assistance, call customer service at:
1-888-786-7287

Chapter 3: SENSUS Device Basics

Checking Battery

With the device in your hand, briefly press and release the button to check the battery (Figure 3). The indicator light will flash green if the battery has sufficient charge. If indicator light flashes red or does not flash at all, the battery needs to be recharged (see below for charging instructions).

Charging Battery

A fully charged battery should provide 20-40 hours of use.

Figure 3.

To charge the battery:

1. Plug the USB cable into the USB port on the side of the device. The USB port is protected by a rubber cover. To access the USB port, rotate the cover until the connector is exposed (Figure 4).
2. Plug the other end of the cable into the AC Adapter (Figure 5). The cable should not be plugged into a computer USB port for charging.
3. The AC Adapter should then be plugged into a standard electrical outlet (Figure 6). The indicator light will show steady green during charging and will turn off when the battery is fully charged. It will take approximately 3 hours to charge an empty battery. When the battery is fully charged, unplug the cable from the device.

A blinking red light indicates that charging has failed.

If the battery is too low to start a therapy session, you can charge the device for approximately 20 minutes to provide enough charge for a single therapy session. To confirm that it has enough charge, disconnect the USB cable from the device and briefly press and release the button. If the indicator light flashes green, there is enough charge. If the indicator light flashes red, reconnect the USB cable and continue charging.

You should never use your SENSUS device with the USB cable connected.

Figure 4.

Figure 5.

Figure 6.

Attaching Electrode

You will need to attach a new electrode prior to first use of the device and every 2 weeks thereafter (can be extended up to 3 days if a new electrode is not available). Two electrodes are included in each pouch. You should reseal the pouch if it contains an electrode. To attach an electrode, snap the electrode into the two connectors as shown in Figure 7.

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Figure 7.

Turn the device so that the snap connectors are visible.

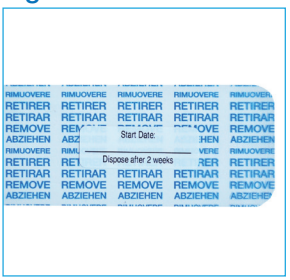
Align the snaps on the electrode to the snap connectors on the device. Insert snaps until they are securely fastened.

Remove the plastic liner covering the electrode (Figure 8) prior to placing the device on your leg. Remember to keep the liner as it should be re-applied to protect the electrode when not in use.

A white label is affixed to each electrode liner (Figure 9). The first time you use a new electrode, write the date on the label. The electrode should be replaced 2 weeks from this date (can be extended up to 3 days if a new electrode is not available).

Figure 8.

Figure 9.



Device Placement

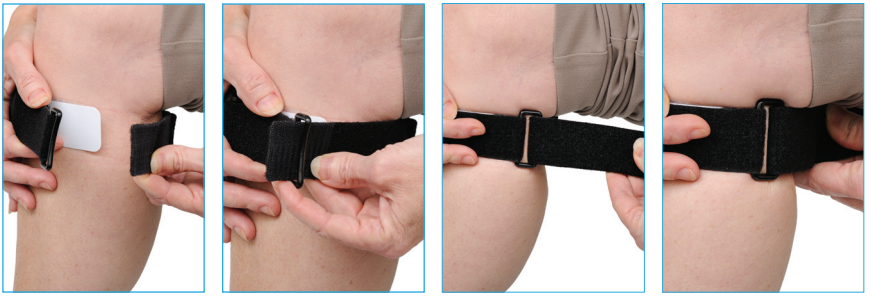
Figure 10.

Place the device on your upper calf about 1-2 inches below the knee (Figure 10). Be sure the electrode is only covering healthy skin that is not irritated and does not have cuts or other wounds. Position the device so that it is comfortable, the button is accessible, the indicator light is visible, and stimulation does not cause discomfort. You may position the device with the button on the inside, outside, or back of the leg; it is your choice. However, you should avoid placing the device on the front of the leg.

If the device cannot be placed in the standard location as shown in Figure 10 then refer to Appendix D for alternate site options.

Loop the strap through the buckle and secure it with the Velcro® fastener as shown in Figure 11. The device should fit securely around your leg and be comfortable to wear. The strap should not be so tight that the device and electrode substantially indent the skin. The electrode should make smooth contact with the skin. If there is buckling of the electrode, loosen the strap, smooth the electrode and re-secure the strap. It is important that each of the four electrode pads are in contact with your skin. If the

Figure 11.



pads are only partially on the skin, then the stimulation may feel uncomfortable.

Your device comes with small, medium and large straps. It is shipped with the medium strap attached. If you require a different strap, remove the medium strap and attach either the small or large strap.

Chapter 4: Configuring SENSUS

Before you begin using your device for the first time you will need to configure it for the right intensity level for you. You should also re-configure your device if you feel that the intensity is no longer providing pain relief. The configuration process consists of placing the device on your leg, pressing the button for 10 seconds to start configuration, then briefly pressing the button every time you feel a tingling sensation under the electrode. Configuration should only take about one minute.

Figure 12.

You should carry out the configuration process in a quiet area without distractions. One comfortable way to configure your

device is seated in a chair, lying in bed or on a sofa with your leg crossed over for easy access (Figure 12). You should not configure within an hour of a therapy session. It is best to configure using a new electrode. If you have difficulty with configuration, call NeuroMetrix customer service at (888) 786-7287.

Configuration Process

STEP 1	Snap electrode to device.
STEP 2	Remove electrode liner and place the device on your upper calf 1-2 inches below knee. The exact position is not critical.
STEP 3	Press and hold button for 10 seconds until the indicator light is steady green. Briefly press the button every time you feel a tingling sensation under the electrode. When the light turns off, configuration is complete. This should take about 1 minute.

If your doctor prescribed two devices, please configure one device at a time. You may configure both devices on one leg, or one device on each leg.

Chapter 5: Pain Therapy with SENSUS

During a therapy session, the device will comfortably stimulate the sensory nerves in your leg to provide pain relief. Each therapy session lasts 60 minutes.

To maximize pain relief, it is important that the stimulation feels strong. However, it should also feel comfortable. The intensity that you will require is estimated based on your configuration. However, because of differences among people, this estimated intensity may be too low, and it will feel weak or too high and may feel uncomfortable. In either case, you should adjust the intensity as described on page 16. The greatest pain relief will be obtained when you set the intensity to the highest level that is also comfortable. The device will remember changes to the intensity and you should not need to adjust the intensity often. Please follow the steps on the following pages for a therapy session.

Preparing for Therapy Session

Before starting a therapy session make sure you have an electrode attached to the device. You should also check the battery to ensure it has an adequate charge.

Place the device on your leg as described in Chapter 3.

Starting Therapy Session

Figure 13.

To start a therapy session, press and hold button (Figure 13) for a few seconds until the indicator light starts blinking green. The indicator light will continue blinking green for the duration of the therapy session.

The intensity will gradually increase to the intensity which was determined when you configured your device. This intensity will be stronger than what you experienced during configuration. You may not feel anything for the first 10-15 seconds. However, the blinking green light indicates the device is functioning properly. Stimulation will continue for a total of 60 minutes. The intensity may feel strong at first but that sensation will typically fade to a comfortable level after a couple of minutes.

Please be patient because it is important for pain relief that the intensity feels strong but comfortable. However, if the intensity is uncomfortable or painful, you should decrease it as described in the next section.

Once your therapy session has begun, you may cover the device with your clothing. You should be careful not to dislodge the device and electrode when covering with clothing. It is best not to wear tight fitting clothing that makes it difficult for you to access the device. You may go about your normal activities during a therapy session. Do not shower, bathe or swim with the device on your leg.

Adjusting Intensity During Therapy Session

Frequent adjustments should not be necessary; however, if the intensity does not feel strong, if it feels uncomfortable, or your calf muscle is twitching, please follow the instructions below:

To decrease the intensity:

- Briefly press the button. Each press will decrease the intensity. Repeat as many times as needed to reach a strong but comfortable intensity.

To increase the intensity:

- Press and hold the button. The intensity will increase while the button is held down. Release the button when the intensity reaches a strong but comfortable intensity.

You may adjust the intensity at any time during a therapy session.

Maximum pain relief will be obtained at the highest intensity level that is also comfortable.

Ending Therapy Session

A therapy session automatically stops after 60 minutes. If the device is in continuous mode, a new therapy session will automatically start 60 minutes following the end of prior session (see page 18 for explanation of continuous mode).

Figure 14.

You can end a therapy session early by tapping the center compartment with your hand twice, while keeping your leg still, as shown in Figure 14. You should not remove the device while it is stimulating, so make sure that the indicator light is not blinking green before removing the device and electrode from your leg.

After completing a therapy session, you may either leave the device on your leg, or remove it. If you remove it, be careful not to damage the electrode and remember to reapply the plastic liner and store the device in the carrying case (see page 20 for instructions on removing electrode).

If you leave the device on your leg for long periods of time, you should check your skin frequently to make sure that it does not get irritated. Chapter 8 provides information on skin care.

Ventilate your skin after wearing for several hours and after overnight use. Refer to Chapter 8 for skin care.

If a problem arises during a therapy session, stimulation will stop and the indicator light will blink red for 10 minutes. Refer to Appendix B for troubleshooting assistance.

Setting Continuous Mode

A device in continuous mode will restart therapy an hour after your last session has completed. This may be convenient if you choose to wear it during sleep or if you need extended pain relief during the day. When you receive your device, continuous mode is off. You may toggle the continuous mode from off to on or vice versa. With the device in your hand, without an electrode attached, press the button for at least 10 seconds, and you will then see either a green or red light. A green light means you are now in continuous mode; a red light means you are now out of continuous mode (i.e., device is in single therapy session mode).

Notes about Continuous Mode

- The first therapy session after toggling continuous mode to on must be started manually. Press and hold the button until indicator light starts blinking green.
- If you are in continuous mode but notice that therapy has not restarted, you may initiate a session manually. There are a few reasons a restart may not have occurred:
  - Previous therapy session was halted by user
  - Device was removed from the skin
  - It has been less than an hour from the last therapy session
  - Battery is low
- Even if you are in continuous mode, you can always start a therapy session at any time. It is recommended that you wait at least 30 minutes following the prior session.

Chapter 6: Using SENSUS During Sleep

Chronic pain often gets worse during the day, reaching its peak at night. As a result, many people with chronic pain have difficulty falling asleep or maintaining high quality sleep throughout the night. You may use SENSUS to provide overnight pain relief to help you sleep better.

You may wear your SENSUS device at bedtime when you are going to sleep and throughout the night. If you would like to have the device automatically start therapy sessions throughout the night then you should set it for continuous mode as described on page 18. However, if you find that the stimulation is waking you up, you should use SENSUS in its single therapy session mode, when falling asleep.

Make sure that your SENSUS device is securely and comfortably placed around your leg before going to sleep.

Ventilate your skin after wearing SENSUS overnight.

If you have any questions regarding overnight use of SENSUS call NeuroMetrix customer service at (888) 786-7287.

Poor sleep can impact your health, safety, and quality of life. Please discuss any concerns you have with your doctor.

Chapter 7: SENSUS Electrodes

The SENSUS Electrodes are designed to operate consistently for at least 2 weeks (can be extended up to 3 days if a new electrode is not available). For best results, you should hydrate your electrode every 2-3 days or if the gel pads are dry.

Figure 15.

Run the electrode under a gentle water stream for 10 seconds as shown in Figure 15. Let air dry for 1 minute before using.

Electrode Removal

Figure 16.

You should be careful not to damage the electrode when you remove it from your upper calf area. To remove the electrode, first unsnap the device so that you have easy access to the electrode. Slowly peel the electrode from your skin, while making sure that each of the gel pads does not separate from the electrode (see Figure 16). Avoid touching the gel with your fingers as that can damage the gel and decrease the life of the electrode. After removal of the electrode you should cover it with the plastic liner.

If you have difficulty removing the electrode, please refer to Chapter 8.

Electrode Storage

Electrodes should always be stored with the plastic liner covering the gel pads. You may snap the electrode into the device for convenient storage. Electrodes should be stored at room temperature out of direct sunlight.

Electrode Replacement

The electrode should be replaced prior to two weeks if stimulation becomes consistently painful despite hydrating the electrode and positioning the device so that the entire electrode is making smooth contact with the skin.

Chapter 8: Skin Care

SENSUS works by electrically stimulating your sensory nerves through your skin. Many people have dry or sensitive skin, and it is important to regularly monitor your skin where it contacts the electrode to ensure that skin irritation does not occur. If your skin becomes irritated, it can make the stimulation uncomfortable. There are some simple things you can do to prevent skin irritation and allow it to heal if it does occur.

Never use the device on open wounds or rashes or over swollen, red, infected, or inflamed skin.

Keep Your Skin Moisturized

Dry skin can make the electrodes difficult to remove which can potentially damage the electrode gel.

If you have dry skin or notice that electrode gel comes off the electrodes you should consider using a light lotion 10 minutes prior to SENSUS use.

Lotions that are light, non-greasy, fast-absorbing, and intended for daily use will work best. Some examples include:

- Aveeno® Daily Moisturizing Lotion
- Lubriderm® Daily Moisture Lotion
- Gold Bond® Skin Therapy Lotion
- Curel® Daily Moisture Lotion

Make sure the lotion has absorbed fully into the skin before placing the electrode and device.

Cleaning and Shaving the Skin

When cleaning the skin, never use harsh soaps or alcohol as they strip away your natural protective barrier and can make the skin more susceptible to irritation. It is not necessary for you to clean your skin immediately before or after using SENSUS. The most important step you can take after using SENSUS is to ventilate the skin that was under the device and electrode.

In general, shaving is not required when using SENSUS. However, if you find that the electrode is not making good contact with the skin then it may be helpful to shave. You should only use an electric razor as razor blades increase the risk of skin irritation.

Ventilate Your Skin

It is important to allow your skin access to open air by frequently removing the device and electrode. Below are some tips for ventilating your skin:

- You should always remove the device after several hours of use during the day or after using overnight
- Alternate legs
- If convenient, remove the device between therapy sessions during the day

Watch for Signs of Skin Irritation

Check your skin after removing the device to watch for signs of potential irritation, including:

- Skin feels itchy while device is on the skin or after removing the device
- Skin is red where electrode was contacting
- Raised or reddened hair follicles

More severe skin reactions such as hives, welts, or blisters are rare.

If your skin itches, please resist the urge to scratch as this will increase irritation. Wait at least 1 day before placing device over the same area.

Protect Your Skin and Let it Heal if Irritation Develops

If you experience skin irritation or generally have sensitive skin, you may consider applying a skin protectant before placing the device and electrode on your leg. Skin protectants are available as wipes, swabs, or sprays. They are safe and serve as a barrier between your skin and the electrode, reducing the likelihood of irritation. They also increase adhesion of the electrode to your skin. Protectants that work well include:

- 3M Cavilon™ No Sting Barrier Film
- Smith & Nephew SKIN-PREP®
- Smith & Nephew No-Sting SKIN-PREP®

These products are available online, including www.amazon.com.

If skin irritation develops then you should not place the device over the irritated area until it completely heals. You may place the device on the other leg or use alternate locations as shown in Appendix D.

Chapter 9: Maintenance, Safety, and Service

Maintenance

Contact your supplier if the device requires service.

Cleaning

Use a damp cloth moistened with mild soap and water to clean the exterior of the device. Do not use any other cleaning solutions since they may damage the case. Never immerse the device in water or other liquids.

Device Storage

When device is not in use, place it in the carrying case and store it in a dry location.

Disposal

Used electrodes should be disposed in normal trash receptacles. Dispose of the device according to national, state, and local regulations as the device contains a Lithium-Ion battery.

Limited Warranty

NeuroMetrix, Inc. manufactures its hardware products in accordance with industry standard practices. NeuroMetrix warrants the SENSUS device to be free from defects in materials and workmanship at the time of shipment. The warranty term is five years beginning on the date of shipment from the manufacturer, as further described in the following text.

This warranty does not cover damage due to external causes, including accident, abuse, misuse, problems with electrical power, usage not in accordance with product instructions, failure to perform required maintenance, and problems caused by use of parts or components not supplied by NeuroMetrix. This warranty does not apply to any product repaired or altered by anyone other than NeuroMetrix or an authorized NeuroMetrix representative.

NeuroMetrix will repair or replace products that are shown to be other than as warranted above and covered under this limited warranty that are returned to NeuroMetrix under a NeuroMetrix issued Return Material Authorization (RMA) Number. To initiate a return contact your supplier.

All parts removed from repaired products will become the property of NeuroMetrix. If NeuroMetrix repairs or replaces a product, the original warranty is not extended.

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ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT REGARDLESS OF THE LEGAL THEORY UPON WHICH SUCH CLAIM IS BASED AND EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY THEREOF.

APPENDIX A: Indicator Light

Indicator Light Status	Explanation
Blinking Green	Stimulating
Steady Green	Configuring or battery charging
Blinking Red	Error
Single Green Flash	Adequate battery charge
Single Red Flash	Battery requires charging

APPENDIX B: Troubleshooting

Configuration:

I cannot start the configuration procedure (light is not steady green).

Make sure the device and electrode are properly placed on the leg and the liner has been removed. Press and hold the button down for at least 10 seconds until the light turns steady green.

I am trying to configure, but I do not feel anything.

It may take 20-30 seconds to first feel the tingling stimulation sensation.

Starting Therapy:

Make sure you are starting therapy correctly by pressing the button for several seconds until the light starts blinking green. Therapy can only be initiated after the device and electrode are securely placed on the calf.

When I start therapy nothing happens (i.e., light is off).

Recharge device.

When I start therapy all I see is a single red blink.

Recharge device.

When I start therapy the light blinks green a few times and stops.

Configure device.

When I start a therapy session the light immediately blinks red.

Generally, a flashing red light indicates that the contact between the electrode and the skin is inadequate. This may occur because the device is not securely placed on the leg or because the electrode is dry or damaged. Wait a few minutes and then restart the therapy session. If this happens again then wait 15 minutes and restart the therapy session. If the problem recurs, then remove the device and inspect the electrode. If the gel is dry then hydrate as described in Chapter 7. Place the device back on the leg making sure that the entire electode is in contact with the skin. Wait a few minutes and restart the therapy session.

Therapy:

The light is blinking green but I do not feel anything.

Wait until therapy has run for at least 2 minutes. If, after 2 minutes, you still cannot feel the stimulation, the intensity is too low. Press and hold the button to increase the intensity until you feel strong but comfortable stimulation. Alternatively, repeat the configuration procedure.

Therapy stopped and the red light is blinking.

Generally, a flashing red light indicates that the contact between the electrode and the skin in inadequate. This may occur because the device is not securely placed on the leg or because the electrode is dry or damaged. Wait a few minutes and then restart the therapy session. If this happens again then wait 15 minutes and restart the therapy session. If the problem recurs, then remove the device and inspect the electrode. If the gel is dry then hydrate as described in Chapter 7. Place the device back on the leg making sure that the entire electrode is in contact with the skin. Wait a few minutes and restart the therapy session.

APPENDIX B: Troubleshooting CONT.

What should I do if stimulation stings or feels uncomfortable?

Turn off the device. Remove the device and inspect the electrode. If the gel is dry, then hydrate the electrode as described in Chapter 7. Place the device and electrode back on your leg, making sure that there is complete contact between the electrode and the skin. If the discomfort persists despite taking these steps then the electrode should be changed.

I am not getting pain relief.

Make sure the stimulation is strong but remains comfortable. Either increase the intensity by pressing and holding the button or repeat the configuration procedure.

Electrode Care:

The gel on my electrode is coming off.

The electrode should still function and can be used as long as the stimulation feels comfortable and the device does not repeatedly blink red during therapy sessions.

The gel sticks to my skin when I remove the electrode.

If the gel is coming off the electrode then use of a light lotion 10 minutes prior to therapy should help (see Chapter 8 in User Manual).

The gel is dry and losing its stickiness.

You should hydrate the electrodes as described in Chapter 7.

Skin Care:

My skin is irritated (redness or rash) or itchy after I remove the device.

Skin irritation may occur. The skin should be ventilated after wearing for several hours and after overnight use by removing the device and electrode from the leg. Legs should be alternated. Chapter 8 provides information on skin care.

If you need assistance, call NeuroMetrix customer service at (888) 786-7287.

APPENDIX C:
Frequently Asked Questions

What should the stimulation feel like?

The stimulation should feel like a buzzing or light pressure sensation. You may reduce the intensity if it feels uncomfortable.

How often can I use SENSUS?

You may start a therapy session whenever you need pain relief. However, it is best to wait 30 minutes between sessions.

When do I need to configure my device?

You must configure the device before first use. You should repeat configuration if you believe that pain relief has diminished. It is best to configure with a new electrode.

If I was prescribed two devices, do I need to match devices and legs?

No, unless the stimulation feels dramatically different between legs.

Will pain relief start immediately after I press the button?

Pain relief usually starts within 15 minutes of start of a therapy session.

Will pain relief continue beyond the end of the therapy session?

Pain relief may last up to 30 minutes after the session ends.

How often do I need to change the electrode?

Every 2 weeks (can be extended up to 3 days if a new electrode is not available).

Can I use SENSUS while sleeping?

You may use it to help you fall asleep and to keep pain under control while sleeping. You may want to set the device for continuous mode in order to obtain overnight pain relief (see page 18).

Can I use my device while showering or bathing?

No.

Are there side effects?

No. You may experience some mild skin irritation under the electrodes with prolonged use.

Can I use it with pain medications?

Your doctor may decide to prescribe both SENSUS and pain medications.

APPENDIX D: Alternate Sites

If your SENSUS device cannot be placed at its usual location just below the knee, such as due to a wound or skin irritation, then it may be positioned at one of the following alternate sites:

- At mid-calf as shown in Figure 17.
- Above the knee on the lower thigh as shown in Figure 18.

You should configure the device at the new site before initiating therapy.

Figure 17.

Figure 18.

APPENDIX E:
SENSUS Technical Specifications

Output

Waveform	Biphasic with alternating leading phase, symmetrical, rectangular
Regulated Current or Voltage	Current
Net Charge per Pulse	0±1 µC into 500Ω load
Maximum Output Voltage (±10%)	100 V
Maximum Output Current (<1KΩ load) (±10%)	100 mA
Pulse Duration (±4%)	200 - 400 µsec
Pulse Frequency (±4%)	60-100 Hz, randomly varying
Pulse Pattern	Continuous
Maximum Phase Charge	20 µC
Maximum Current Density	0.71 mA/cm^2 into 500Ω load
Maximum Average Current	4 mA into 500Ω load
Maximum Average Power Density	7 mW/cm^2 into 500Ω load

Output Trips

No Load	Device not connected to patient
Insufficient Charge	Delivered charge below target
Over Load	Delivered charge above target
Short Circuit	Low impedance
Electrode Peeling	Electrode dislodging from skin

APPENDIX E:
SENSUS Technical Specifications CONT.

Therapy Session

Timer	60 minutes
Start Stimulation	Press button down for more than 2 seconds
Halt Stimulation	Tap center compartment twice with hand
Intensity Increase/Decrease	0.5 - 2 mA/sec above sensation threshold
Habituation Compensation	Adaptive stepwise increase in intensity of during session

Electrode

Type	Self-adhering, single-patient use, multiple applications
Materials	Mylar substrate, silver electrode pads
Number of Electrodes	2, outer electrode area 28 cm^2, inner electrode area 33 cm^2
Connector	Medical snap (male)
Dimensions	0.2 cm x 5.3 cm x 28.3 cm (exterior)

Power

Source	Permanent rechargeable battery
Battery Type	Rechargeable 3.7V Lithium-Ion battery
Charging Source	AC line adapter or connection to powered USB port
Line Current Isolation	Patient disconnected when charging

Power continued

Patient Leakage Current, DC	< 10 µA
Patient Leakage Current, Enclosure	< 100 µA

Physical

Dimensions	176 mm x 63 mm x 18 mm
Weight	82 g

Environmental

Operating Temperature Range	10° C to 40° C
Atmospheric Pressure Range	50 kPa to 106 kPa
Relative Humidity Range	30% to 75%
Transport and Storage Temperature Range	-40° C to 50° C
Atmospheric Pressure Range	50 kPa to 106 kPa
Relative Humidity Range	10% to 90%

Guidance Documents & Standards

FDA	Draft Guidance for Industry and Staff: Class II Special Control Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief (April 5, 2010)
IEC	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 62304

APPENDIX F: Prescribing Information

UNITED STATES FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR LICENSED MEDICAL PROFESSIONAL.

Indications

The NeuroMetrix SENSUS is intended for use as a transcutaneous electrical nerve stimulator for the symptomatic relief and management of chronic intractable pain.

Contraindications

- Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death.
- The device should not be used on patients whose pain syndromes are undiagnosed.

Precautions

- Transcutaneous electrical nerve stimulation is not effective for pain of central origin, including headache.
- Transcutaneous electrical nerve stimulation is not a substitute for pain medications and other pain management therapies.
- Transcutaneous electrical nerve stimulation devices have no curative value.
- Transcutaneous electrical nerve stimulation is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
- Effectiveness is highly dependent upon patient selection by a licensed medical professional qualified in the management of pain patients.

- The long-term effects of electrical stimulation are unknown.
- Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head.
- The safety of electrical stimulation during pregnancy has not been established.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
- Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians.
- Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.
- Use caution when the patient has a tendency to bleed internally, such as following an injury or fracture.
- Use caution following recent surgical procedures when stimulation may disrupt the patient's healing process.
- Use caution if stimulation is applied over the menstruating or pregnant uterus.
- Use caution if stimulation is applied over areas of skin that lack normal sensation.
- Keep this device out of the reach of children.
- Use this device only with the leads, electrodes, and accessories recommended by the manufacturer.
- Use this device only under the continued supervision of a licensed medical professional.

APPENDIX F:
Prescribing Information CONT.

- Accessory equipment connected to the USB port must be certified to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Most computers manufactured by major suppliers meet the IEC 60950 standard. If in doubt, consult with your local information technology support.

Adverse Reactions

- Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin.
- Patients may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes and to the head and face.
- Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

Warnings

- Do not apply stimulation over the neck because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- Do not apply stimulation across the chest because the introduction of electrical current into the chest may cause rhythm disturbances to the heart, which could be lethal.

- Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).
- Do not apply stimulation over, or in proximity to, cancerous lesions.
- Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.
- Do not apply stimulation when in the bath or shower.
- Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put the patient at risk of injury.
- Consult with the patient's physician before using this device, because it may cause lethal rhythm disturbances to the heart in susceptible individuals.
- Apply stimulation only to normal, intact, clean, healthy skin.
- No modification of this device is allowed.

APPENDIX G: Symbols

User Manual/device labeling

Type BF Applied Part

WEEE (Waste Electronic and Electrical Equipment) symbol in accordance with council directive 2002/96/EC

MN Abbreviation for model number

APPENDIX H: Electromagnetic Compatibility Declaration

SENSUS is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions; CISPR 11	Group 1	SENSUS uses RF energy only for its internal function. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions; CISPR 11	Class B	SENSUS is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Electrostatic Discharge Immunity (ESD); IEC 61000-4-2	±6kV contact; ±8kV air	Floors should be wood, concrete or ceramic tile.
Radiated RF; IEC 61000-4-3	3 V/m; 80 MHz to 2.5 GHz	3 V/m compliance level

NEUROMetrix®

62 Fourth Avenue
Waltham, MA 02451
(888) 786-7287
www.SENSUSRx.com

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